IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD	:	
v.	:	CIVIL NO. 17-cv-01065-MSG-RL
BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC.	:	

MEMORANDUM CONCERNING PLAINTIFFS' MOTION FOR MORE COMPLETE INTERROGATORY ANSWERS (DOC. 234)

INTRODUCTION

Plaintiffs (collectively, "AbbVie") have filed a request (which I call a motion in this Memorandum) to compel a more complete response to their Interrogatory No. 21,[1] which concerns the defendants' (collectively, "Boehringer") launch plans for its biosimilar drug. Doc. No. 234 ("Pl. Mot."). AbbVie argues that evidence of Boehringer's launch plans is relevant to refuting Boehringer's "unclean hands" defense. *Id.* at 2-3. AbbVie explains that Boehringer has indicated in public statements that it "intends to launch its biosimilar adalimumab product *before* AbbVie's patents expire," and that such an intention or plan "would directly contradict Boehringer's claim that AbbVie's patents are somehow improperly keeping Boehringer off the market." *Id.* at 3. AbbVie also claims that if Boehringer is "stockpiling product that can be commercially sold," in anticipation of a launch, the stockpiling would infringe AbbVie's patent claims. *Id.*

[1] The Interrogatory asks Boehringer to "[i]dentify any anticipated, projected, or intended launch date of BI 695501 considered by Boehringer, including but not limited to a description of any decision, plan, or preparation to launch or not launch BI 695501 before the expiration of any of the Patents-in-Suit." Pl. Mot. at 2.

AbbVie argues that the proposed discovery is appropriate and not unduly burdensome. *Id.* at 4-5. AbbVie also argues that the BPCIA does not restrict inquiry into Boehringer's launch plans.

Boehringer argues that the BPCIA has a "carefully calibrated scheme" that provides for notice of launch plans 180 days in advance of launch. Doc. No. 243 at 2 ("Def. Opp.") (citing to *Sandoz Inc. v. Amgen Inc.,* 137 S.Ct. 1664, 1670-71 (2017)). Early disclosure of launch plans will, on Boehringer's account, disrupt this statutory scheme. *Id.* (citing to *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 15-1455, 2017 WL 3676745 at *2 (E.D. Tex. Aug. 25, 2017) and *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.,* 99 F. Supp. 3d 461, 471-72 (D.N.J. 2015)). Boehringer also argues that early disclosure of its launch plans would not be relevant to its unclean hands defense. Def. Opp. at 3-4.

I will address the BPCIA argument first, then the more conventional arguments about relevance and proportionality.

DISCUSSION

A. The proposed discovery is not inconsistent with the BPCIA's litigation management scheme.

The language of the BPCIA does not expressly prevent or limit discovery in a biosimilar case, once litigation begins. Boehringer's argument is that the structure of the BPCIA provides for an echeloned dispute resolution process, the last phase of which is triggered by notice of an applicant's intent to commercially market a biosimilar drug covered by the statute.[2] Boehringer contends that the discovery sought by AbbVie will

[2] 42 U.S.C. §262(l)(8)(A) provides that the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. §262(l)(8)(B) provides that after receiving notice, the "reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement. . ."

reveal or suggest Boehringer's launch plans, disclosing valuable competitive information and upsetting the careful balance wrought by the BPCIA.

Boehringer reads too much into the statute. The BPCIA's sequenced litigation process is designed to channel patent disputes involving biosimilar drugs into several successive stages: pre-litigation disclosure and negotiation; phase I litigation, which tests infringement claims for representative patents[3]; and phase II litigation, in which the balance of issues in the dispute may be resolved. *Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 1664, 1670-71 (2017). A "sponsor" – the manufacturer of the patented drug, or "reference drug" – can begin phase II litigation once the applicant has provided 180 days' notice of its intent to commercially launch its biosimilar product. As part of phase II litigation, the sponsor can seek a preliminary injunction to prevent the launch of the biosimilar. Before the 180-day notice is filed, a preliminary injunction is off the table. *Id.*

The 180-day notice requirement is not designed to cloak launch plans with a broad ranging privilege against disclosure before the notice is filed. It is designed to avoid a preliminary injunction proceeding unless one is needed, that is, because a commercial launch is planned in six months. It is also designed to provide a reasonable period of 180 days within which to resolve the preliminary injunction, rather than the usual highly compressed time schedule forced on the parties and court by a commercial launch. Nothing in the statute says that otherwise relevant and discoverable launch plans may be withheld because the 180-day time clock has not been triggered.

The cases cited to by Boehringer hold that the Hatch-Waxman Act does not require a party to give early notice of its intent to launch, and that it is not good policy

---

[3] The selection process is controlled to a large extent by the biosimilar applicant, here, Boehringer.

for a judge to impose such a requirement on a party. *See Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 15-1455, 2017 WL 3676745 at *2 (E.D. Tex. Aug. 25, 2017); *Otsuka Pharm. Co. v. Torrent Pharm. Ltd., Inc.,* 99 F. Supp. 3d 461, 471-72 (D.N.J. 2015). The BPCIA, unlike Hatch-Waxman, does require advance notice of launch plans for those proceeding under the BPCIA. But requiring Boehringer to answer discovery about its launch plans is not the same as issuing an order compelling advanced notice of intent to launch under the BPCIA, with all its consequences. Boehringer would not be bound by the disclosure of contingent plans,[4] and AbbVie would not be authorized under the BPCIA to initiate a preliminary injunction proceeding, if the discovery revealed that Boehringer has reached an internal decision about when it will launch. Requiring Boehringer to answer Interrogatory 21 is not inconsistent with requirements of the BPCIA. I will turn to Boehringer's other arguments.

B. The proposed discovery is relevant to the unclean hands defense.

AbbVie explains that if the discovery reveals that Boehringer has largely or completely disregarded or discounted the "patent thicket" in formulating its launch plans, this would tend to undermine Boehringer's argument that the "patent thicket" has harmed Boehringer by slowing down the launch of Boehringer's biosimilar product. Boehringer insists that its launch plans are irrelevant to its unclean hands defense and explains that the "patent thicket" has harmed Boehringer and the public in different ways.

"A determination of relevance implicates substantive patent law. Therefore, we look to Federal Circuit law rather than regional circuit law in discussing relevance."

[4] It may be commercially disadvantaged, and unfairly so, but that is a different argument entirely, and is addressed below.

Micro Motion, Inc. v. Kane Steel Co., Inc., 894 F.2d 1318, 1326 n.8 (Fed. Cir. 1990) (citing to *Truswal Sys. Corp. v. Hydro–Air Eng'g, Inc.,* 813 F.2d 1207, 1211–12 (Fed. Cir. 1987)). "Unclean hands" is a defense to a cause of action for infringement. *See Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369, 1380 (Fed. Cir. 2001) (citing to *Keystone Driller Co. v. General Excavator Co*., 290 U.S. 240, 243-44 (1933)). A patent holder's "unclean hands" may bar it from receiving equitable relief. *See Gilead Sciences, Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1240 (Fed. Cir. 2018). The defense requires that "'misconduct' of a party seeking relief 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation[.]'" *Id.* at 1239 (quoting from *Keystone*, 290 U.S. at 245). The misconduct must "in some measure affect the equitable relations between the parties in respect of something brought before the court." *Id.* Wide-ranging misconduct may invalidate an entire group of related patents. *See Consolidated Aluminum Corp. v. Foseco Intern. Ltd.,* 910 F.2d 804, 809 (Fed. Cir. 1990).

In some patent contexts, the Federal Circuit has required an explicit causal connection between the alleged misconduct underlying a claim of unclean hands and prejudice to the party asserting unclean hands. *See Serdarevic v. Advanced Medical Optics, Inc.,* 532 F.3d 1352, 1361 (Fed. Cir. 2008) ("a plaintiff relying on the unclean hands doctrine to defeat a defense of laches must show not only that the defendant engaged in misconduct, but moreover that the defendant's misconduct was responsible for the plaintiff's delay . . ."). Other circuit courts require proof that the wrongful conduct comprising "unclean hands" actually has injured the party claiming the defense. *See Mitchell Bros. Film Group v. Cinema Adult Theater*, 604 F.2d 852, 863 (5th Cir. 1979) ("alleged wrongdoing of the plaintiff does not bar relief unless the defendant can

show that he has personally been injured by the plaintiff's conduct[]" (citation omitted)). The Federal Circuit does not go this far. In *Gilead,* the court rejected the invitation to add a "materiality" element to the "unclean hands" defense. 888 F.3d at 1240. The court held that the wrongful conduct had to have only an "immediate and necessary relation" to the litigation between the parties. *Id.* Actual injury is not an element of the "unclean hands" defense: "the standard can cover at least some misconduct that ultimately fails to affect the litigation, as when it is discovered before it bears fruit, as long as its objective potential to have done so is sufficient." *Id.*

I will assume that Boehringer need not prove that AbbVie's alleged "unclean hands" caused actual injury to Boehringer's business. That is not the end of the relevance inquiry, however.

Evidence is relevant if it tends to make a fact of consequence to the litigation more (or less) probable. Fed. R. Evid. 401. "The Rule's basic standard of relevance thus is a liberal one." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 587 (1993). Relevance is "a relation between an item of evidence and a matter properly provable in the case," *See Sprint/United Management Co. v. Mendelsohn,* 552 U.S. 379, 387–88 (2008) (quoting from the Advisory Committee Notes to Fed. R. Evid. 401).

If harm to Boehringer is not a formal element of the "unclean hands" defense, Boehringer may still establish that AbbVie's "patent thicket"[5] caused injury to Boehringer because it makes for a coherent and compelling narrative or explains AbbVie's motive for creating the "patent thicket." These are well-established "facts . . . of consequence" that anchor a finding of relevance. *See Old Chief v. United States,* 519 U.S.

[5] AbbVie does not concede the existence of unclean hands in the formation or enforcement of its patent estate. I make no finding on whether an unclean hands defense has been established.

172, 188-89 (1997) (coherent and compelling narrative); *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1367 (Fed. Cir. 2007) (motive is evidence from which intent may be inferred). Certainly, AbbVie's motive to harm Boehringer (and other competitors), and AbbVie's success at harming competition, seem to be central to Boehringer's account of AbbVie's "unclean hands" in Boehringer's "Second Supplemental Objections and Responses to Plaintiff's Interrogatory (No. 20)."[6]

Boehringer's response to Interrogatory No. 20 says that "AbbVie has engaged in a multifaceted, illegal scheme to prevent the sale of adalimumab in competition against Humira[,]®" and that "AbbVie's intensive desire to create a patent thicket encouraged and fostered an unconscionable pattern of withholding and/or misrepresenting information to the U.S. Patent and Trademark Office . . ." IA at 5. Boehringer also says that "AbbVie's program was successful in creating a thicket that AbbVie has exploited to delay competition of an FDA-approved adalimumab biosimilar" and that "AbbVie's misconduct . . . harms the public, including the Defendants, and renders its assertion of its patents violative of principles of equity." *Id.* at 5-6.

Boehringer says that AbbVie generated "a vast portfolio of dubious, overlapping patents years after the launch of Humira®" which were "designed to prevent an adalimumab biosimilar . . ." *Id.* at 7. All this was "part of a larger scheme to thwart adalimumab competition." *Id.* at 10. After identifying a wide variety of alleged misrepresentations and material omissions in connection with adalimumab related patent applications, Boehringer contends that "AbbVie's business strategy has been to

[6] I will refer to this document as "IA." References to this interrogatory answer are taken from the copy emailed to me by counsel on February 14, 2019, and the pagination noted in this Memorandum was that used in the copy sent to me. Because the parties have indicated that the document contains confidential information, I will not file the interrogatory answer.

leverage its thicket of dubious and overlapping patents to delay biosimilar competition." *Id.* at 30. Boehringer goes on to contend that "AbbVie has an ulterior motive for using the BPCIA process and patent litigation to delay Defendants' entry onto the market, and thus obtain an unfair advantage over competitors to maintain its 'dominant position' in the marketplace." *Id.* at 33.

Though I agree with Boehringer that commercial injury to Boehringer is not a prerequisite to establishing an unclean hands defense, Boehringer's account of the motive for, and consequences of, AbbVie's alleged misconduct put the issue front and center. The degree to which the "patent thicket" delayed Boehringer's launch may have a legitimate impact on a fact-finder's assessment of whether AbbVie has unclean hands. At least, that is the import of Boehringer's explication of its unclean hands defense in its answer to Interrogatory 20. Certainly, the harm or intended harm to Boehringer may weigh in the decision whether to apply the doctrine of unclean hands. The weight given to the "patent thicket" by Boehringer when making its launch plans is thus a fact of consequence to the defense of "unclean hands," in large measure because Boehringer has made it so. Fed. R. Civ. Pro. 26(b)(1); Fed. R. Evid. 401(a) and (b). In short, if Boehringer argues – as it does - that the purpose and effect of the "patent thicket" was to delay competition and damage competitors, and seeks to prove this purpose and effect, it cannot refuse to quantify the delay and the damage. That would be unfair.

Relevance is not a daunting hurdle, and AbbVie's theory clears it.[7]

[7] Evidence does not have to be conclusive or even powerfully convincing to be relevant. *See United States v. Clifford,* 704 F.2d 86, 90 (3d Cir. 1983) ("A piece of evidence . . . need not conclusively prove a fact beyond a reasonable doubt in order to be admissible."). A piece of evidence need only be a brick, not a wall. *See United States v. Kemp,* 500 F.3d 257, 295 (3d Cir. 2007) (citing to the Advisory Committee Notes to Fed. R. Evid. 401)).

C. I will permit limited discovery of launch plans.

As with most discovery disputes, a determination of relevance is not dispositive. Of more significance is the question of whether the discovery is proportionate to its burdens, under Federal Rule of Civil Procedure 26(b)(1), in light of the considerations listed in the rule. I make the following findings, guided by Rule 26(b)(1)'s considerations:

- The "unclean hands" defense has become important to this action, as a result of Boehringer's theory of the case. I conclude that while injury to Boehringer is not an element of the defense, the impact of the "patent thicket" on Boehringer's launch plans is likely to have some relevance to the establishment or deconstruction of the defense.
- Boehringer has better access to the information than does AbbVie.
- The parties' resources are vast.
- The broad discovery sought in Interrogatory 21 is unlikely to be critical to the resolution of the "unclean hands" defense. Commercial injury to Boehringer is not determinative of whether AbbVie engaged in misconduct amounting to unclean hands. Parsing out the effect of the "patent thicket" on Boehringer's launch plans is likely to be laborious and inconclusive.
- The burden of the discovery on Boehringer is likely to be significant. The information is of intense competitive interest and value to both sides. Developing business intelligence is not a legitimate purpose of discovery. When measuring proportionality, it is appropriate to consider outsized commercial effects of the proposed discovery against the discovery's more limited utility in resolving core legal issues in a case. *See Card-Monroe Corp. v. Tuftco Corp,* 2015 WL 11110143,

at *2 (E.D.Tenn., 2015) (the party seeking broad discovery failed to meet its burden of making a particularized showing of relevance and proportionality to the issues in the case of sensitive competitive information, in light of the parties' position as direct competitors); *hibu Inc. v. Peck,* 2017 WL 2472548, at *3 (D.Kan., 2017) (revenue information from every state was overbroad, as related to issues in the case, and raised concerns about disclosure of proprietary information in a highly competitive industry).

- I find that a response to Interrogatory No. 21 likely will require a significant, time-consuming and expensive effort to identify and segregate privileged and work-product information. Attorneys may not have been the final decision makers, as to launch plans, but likely were integral to the assessment of the impact of the "patent thicket," and attendant litigation, on the commercial launch of a biosimilar. I will stage the discovery to postpone the resolution of privilege and work-product claims.
- I find that a more limited approach to the discovery sought in Interrogatory 21 is likely to produce probative evidence relevant to the defense of unclean hands, as it has been framed by Boehringer, with considerably less cost and burden. *See* Fed. R. Civ. Pro. 37(a)(5)(B) (permitting the granting in part and denial in part of a motion to compel, and entry of "any protective order authorized under Rule 26(c)"); *see* Fed. R. Civ. Pro. 26(c)(1)(C) (a protective order may prescribe "a discovery method other than the one selected by the party seeking discovery.").
- I will require that Boehringer state whether it contends that the "patent thicket" Boehringer alleges as part of its unclean hands defense delayed Boehringer's launch plans for its biosimilar drug. If Boehringer does not contend that the

"patent thicket" delayed its launch plans, that will be an end to the discovery dispute. AbbVie may use the answer for any appropriate purpose.

- Boehringer also will state whether it contends that evidence of delayed launch plans is admissible to prove its unclean hands defense.
- If Boehringer contends that evidence of delayed launch plans is admissible to prove its unclean hands defense, it will supply an interrogatory answer explaining a) when it would have launched its biosimilar drug, absent the "patent thicket," b) by how much time the launch was delayed by the "patent thicket," c) exactly how the "patent thicket" operated to delay its launch plans, and d) a calculation of the damages, if any, incurred as a result of the delay. The damage calculations will provide a detailed explanation of the assumptions and information relied upon in making the calculations and will otherwise comply with the requirements of Fed. R. Civ. Pro. 26(a)(1)(A)(iii). Boehringer will identify and produce all non-privileged, non-work-product documents relevant[8] to its answers. If Boehringer relies in part on documents previously produced, it will identify them.

[8] I consider a document "relevant" if
(1) it includes information that would not support the disclosing parties' contentions;
(2) it includes those persons who, if their potential testimony were known, might reasonably be expected to be deposed or called as a witness by any of the parties;
(3) it is information that is likely to have an influence on or affect the outcome of a claim or defense;
(4) it is information that deserves to be considered in the preparation, evaluation or trial of a claim or defense; and
(5) it is information that reasonable and competent counsel would consider reasonably necessary to prepare, evaluate, or try a claim or defense.
See U. S. Dist. Ct. Rules E.D.Tex., Rule CV-26(d), *Provisions Governing Discovery; Duty of Disclosure*. This definition is well-known to experienced patent counsel.

- If Boehringer withholds privileged[9] or work-product protected documents, it will submit a privilege log that satisfies the requirements of Fed. R. Civ. Pro. 26(b)(5) by providing (at least) a) a description of the document that will be meaningful to a reviewing judge, b) the Bates-stamp number of the document, c) the name of the attorney involved in the communication or preparation of the document, d) the date the document was prepared, e) a description of the purpose of the document that establishes its privilege or work-product status.
- The parties will meet and confer promptly about the discovery required in this Order. Among other matters, the parties will discuss the production of launch related documents and information under an "attorneys' eyes only" agreement. If issues remain and cannot be resolved, the parties will initiate a call with me, and provide me with a joint letter explaining the dispute.

D. Evidence of stockpiling is potentially relevant to infringement, but additional discovery is disproportionate at this point in the litigation.

AbbVie argues that if Boehringer is making its biosimilar in quantities that indicate it is stockpiling for a commercial launch, this would be an act of infringement. Pl. Mot. at 4. Not necessarily. Likely at issue is the "safe harbor" provision of 35 U.S.C. § 271(e)(1), under which Boehringer may make an allegedly infringing product "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). If the evidence at trial indicates that Boehringer's biosimilar drug infringed, and that some of its batches were made for

[9] Assertions of attorney-client privilege in a mixed legal and business environment are fraught. *See* Doc. No. 127, at 2 (evaluations of the competitive positions of companies predominantly reflecting business concerns are not subject to attorney-client privilege) (quoting from Boehringer's motion to compel).

commercial delivery, and not for developing information as part of the approval process, AbbVie has a point.

Boehringer says AbbVie's theory has lain unattended for much of the case and is make-weight. Def. Opp. 5-7. Boehringer also points out that it has supplied lots of detailed information about all the batches of biosimilar drug it has manufactured. *Id*. Boehringer has a point. AbbVie does not make a convincing case that additional stockpiling discovery is needed or will matter to the disposition of infringement issues in this case. I find that additional discovery on the subject is of minimal value and disproportionately burdensome. I will deny the motion to compel an answer about stockpiling.

CONCLUSION

I will grant AbbVie's motion in part and deny it in part and direct the parties to engage in limited discovery on the subject. An Order will be entered consistent with this Memorandum.

BY THE COURT:

s/Richard A. Lloret
RICHARD A. LLORET
U.S. MAGISTRATE JUDGE